Complete Summary

GUIDELINE TITLE

Clinical practice guidelines for the sustained use of sedatives and analgesics in the critically ill adult.

BIBLIOGRAPHIC SOURCE(S)

Clinical practice guidelines for the sustained use of sedatives and analgesics in the critically ill adult. Am J Health Syst Pharm 2002 Jan 15;59(2):150-78. [235 references] PubMed

Jacobi J, Fraser GL, Coursin DB, Riker RR, Fontaine D, Wittbrodt ET, Chalfin DB, Masica MF, Bjerke HS, Coplin WM, Crippen DW, Fuchs BD, Kelleher RM, Marik PE, Nasraway SA Jr, Murray MJ, Peruzzi WT, Lumb PD. Clinical practice guidelines for the sustained use of sedatives and analgesics in the critically ill adult. Crit Care Med 2002 Jan;30(1):119-41. [235 references] PubMed

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Pain and discomfort
- Agitation
- Delirium
- Sleep deprivation

GUIDELINE CATEGORY

Evaluation
Treatment

CLINICAL SPECIALTY

Anesthesiology
Critical Care
Emergency Medicine
Neurology
Nursing
Pediatrics
Pharmacology
Pulmonary Medicine

INTENDED USERS

Advanced Practice Nurses
Nurses
Pharmacists
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide recommendations for the sustained use of sedatives and analgesics in the critically ill adult

TARGET POPULATION

Critically ill patients

Note: This document pertains to patients older than 12 years. The majority of the discussion focuses on the care of patients during mechanical ventilation.

INTERVENTIONS AND PRACTICES CONSIDERED

Assessment

Pain assessment

1. Patient self-report
2. Verbal Rating Scale (VRS)
3. Visual Analogue Scale (VAS)
4. Numeric Rating Scale
5. McGill Pain Questionnaire (MPQ)
6. Wisconsin Brief Pain Assessment (BPQ)
7. Behavior-Physiologic Scale
8. Verbal Descriptive Scale
9. Surrogate Assessment

Sedation assessment

1. Ramsay Scale
2. Riker Sedation-Agitation Scale
3. Motor Activity Assessment Scale
4. Vancouver Interaction and Calmness Scale

5. Observer´s Assessment of Alertness/Sedation Scale
6. COMFORT Scale
7. Objective assessment (e.g., Bispectral Index)

Delirium assessment

1. Clinical history and evaluation as guided by Diagnostic and Statistical Manual of Mental Disorders, 4th edition.
2. Confusion Assessment Method for the Intensive Care Unit (CAM-ICU)

Sleep assessment

1. Patient self report
2. Systemic observation
3. Visual Analogue Scale

Treatment

Analgesia therapy

1. Nonpharmacologic interventions, including attention to proper positioning of patients, stabilization of fractures, elimination of irritating physical stimulation, and application of heat or cold
2. Pharmacologic therapy, including opioids (e.g., fentanyl, hydromorphone, morphine, remifentanil), nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, ketorolac, naproxen), and acetaminophen

   Note: Meperidine, codeine, and analgesics with agonist-antagonist activity, such as nalbuphine, butorphanol, and buprenorphine, are considered but not recommended.

Sedation therapy

1. Benzodiazepines, including diazepam, lorazepam, midazolam
2. Propofol (Diprivan)
3. Benzodiazepine antagonists (considered but not recommended)
4. Central alpha-agonists including clonidine and dexmedetomidine

Delirium therapy

1. Neuroleptic agents including chlorpromazine and haloperidol

Treatment for sleep deprivation

1. Nonpharmacologic sleep strategies, such as environment modification, relaxation, back massage, music therapy, ear plugs, single rooms, and lighting mimicking
2. Pharmacologic therapy with sedatives-hypnotics, such as benzodiazepines or zolpidem

MAJOR OUTCOMES CONSIDERED

- Accuracy and reliability of assessment instruments
- Comfort/pain level
- Awakening time
- Time to extubation
- Adequacy of sedation
- Presence of delirium
- Sleep
- Drug side effects

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A comprehensive literature search was performed to develop the clinical practice guideline. Published studies identified through a MEDLINE search (Sedation and Analgesia 1994-2001) were reviewed, as were the reference lists of the retrieved documents and abstracts from meetings of professional associations. The literature was critically evaluated for research design, patient selection, medication dose, administration route, combination treatment, test measures, statistics, and results.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Categories (Levels) of Literature Evaluation:

1. Results from a single prospective, randomized, controlled trial or from a meta-analysis of prospective, randomized, controlled trials
2. Results from a single prospective, randomized, controlled trial or from a meta-analysis of prospective, randomized, controlled trials, in which the confidence interval for the treatment effect overlaps the minimal clinically important benefit
3. Results from nonrandomized, concurrent, cohort studies
4. Results from nonrandomized, historical, cohort studies
5. Results from case studies
6. Recommendations based on expert opinion

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The medical literature ranged in quality from prospective randomized trials and retrospective observations to expert opinions. After the authors identified and classified their respective studies, they graded the articles on the basis of the results of the review. Pertinent references were assigned a score to account for variance in quality. The recommendations of the Society of Critical Care Medicine, American College of Critical Care Medicine, and the American Society of Health-System Pharmacists (Joint Task Force) were graded according to the strength and quality of the scientific evidence. A substantial effort was made by the Joint Task Force to adhere to the methodology for developing a scientifically sound clinical practice guideline as prescribed by the American Medical Association, the Institute of Medicine, and the Canadian Medical Association.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendations:

A. Methods strong, results consistent, prospective, randomized, controlled trials, no heterogeneity
B. Methods strong, results inconsistent, prospective, randomized, controlled trials, heterogeneity present
C. Methods weak, observational studies

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The grades of recommendations (A-C) are defined at the end of the "Major Recommendations" field.

1. All critically ill patients should have the right to adequate analgesia and management of their pain. (Grade of recommendation = C)
2. Pain assessment and response to therapy should be performed regularly by using a scale appropriate to the patient population and systematically documented. (Grade of recommendation = C)
3. The level of pain reported by the patient must be considered the current standard for assessment of pain and response to analgesia whenever possible. Use of the numeric rating scale (NRS) is recommended to assess pain. (Grade of recommendation = B)
4. Patients who cannot communicate should be assessed through subjective observation of pain-related behaviors (movement, facial expression, and posturing) and physiological indicators (heart rate, blood pressure, and respiratory rate) and the change in these parameters following analgesic therapy. (Grade of recommendation = B)
5. A therapeutic plan and goal of analgesia should be established for each patient and communicated to all caregivers to ensure consistent analgesic therapy. (Grade of recommendation = C)
6. If intravenous doses of an opioid analgesic are required, fentanyl, hydromorphone, and morphine are the recommended agents. (Grade of recommendation = C)
7. Scheduled opioid doses or a continuous infusion is preferred over an "as needed" regimen to ensure consistent analgesia. A patient controlled analgesia (PCA) device may be utilized to deliver opioids if the patient is able to understand and operate the device. (Grade of recommendation = B)
8. Fentanyl is preferred for a rapid onset of analgesia in acutely distressed patients. (Grade of recommendation = C)
9. Fentanyl or hydromorphone are preferred for patients with hemodynamic instability or renal insufficiency. (Grade of recommendation = C)
10. Morphine and hydromorphone are preferred for intermittent therapy because of their longer duration of effect. (Grade of recommendation = C)
11. Nonsteroidal anti-inflammatory drugs (NSAIDs) or acetaminophen may be used as adjuncts to opioids in selected patients. (Grade of recommendation = B)
12. Ketorolac therapy should be limited to a maximum of five days, with close monitoring for the development of renal insufficiency or gastrointestinal bleeding. Other nonsteroidal anti-inflammatory drugs may be used via the enteral route in appropriate patients. (Grade of recommendation = B)
13. Sedation of agitated critically ill patients should be started only after providing adequate analgesia and treating reversible physiological causes. (Grade of recommendation = C)
14. A sedation goal or endpoint should be established and regularly redefined for each patient. Regular assessment and response to therapy should be systematically documented. (Grade of recommendation = C)
15. The use of a validated sedation assessment scale (Riker Sedation-Agitation Scale, Motor Activity Assessment Scale, or Vancouver Interaction and Calmness Scale) is recommended. (Grade of recommendation = B)
16. Objective measures of sedation, such as bispectral index, have not been completely evaluated and are not yet proven useful in the intensive care unit (ICU). (Grade of recommendation = C)

17. Midazolam or diazepam should be used for rapid sedation of acutely agitated patients. (Grade of recommendation = C)
18. Propofol is the preferred sedative when rapid awakening (e.g., for neurologic assessment or extubation) is important. (Grade of recommendation = B)
19. Midazolam is recommended for short-term use only, as it produces unpredictable awakening and time to extubation when infusions continue longer than 48–72 hours. (Grade of recommendation = A)
20. Lorazepam is recommended for the sedation of most patients via intermittent intravenous administration or continuous infusion. (Grade of recommendation = B)
21. The titration of the sedative dose to a defined endpoint is recommended with systematic tapering of the dose or daily interruption with retitration to minimize prolonged sedative effects. (Grade of recommendation = A)
22. Triglyceride concentrations should be monitored after two days of propofol infusion, and total caloric intake from lipids should be included in the nutrition support prescription. (Grade of recommendation = B)
23. The use of sedation guidelines, an algorithm, or a protocol is recommended. (Grade of recommendation = B)
24. The potential for opioid, benzodiazepine, and propofol withdrawal should be considered after high doses or more than approximately seven days of continuous therapy. Doses should be tapered systematically to prevent withdrawal symptoms. (Grade of recommendation = B)
25. Routine assessment for the presence of delirium is recommended. (The Confusion Assessment Method – Intensive Care Unit is a promising tool for the assessment of delirium in intensive care unit patients.) (Grade of recommendation = B)
26. Haloperidol is the preferred agent for the treatment of delirium in critically ill patients. (Grade of recommendation = C)
27. Patients should be monitored for electrocardiographic changes (QT interval prolongation and arrhythmias) when receiving haloperidol. (Grade of recommendation = B)
28. Sleep promotion should include optimization of the environment and nonpharmacologic methods to promote relaxation with adjunctive use of hypnotics. (Grade of recommendation = B)

Definitions:

Grades of Recommendations:

A. Methods strong, results consistent, prospective, randomized, controlled trials, no heterogeneity
B. Methods strong, results inconsistent, prospective, randomized, controlled trials, heterogeneity present
C. Methods weak, observational studies

CLINICAL ALGORITHM(S)

An algorithm is provided in the original guideline document for the sedation and analgesia of mechanically ventilated patients.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for select recommendations (see the "Major Recommendations" field). The medical literature ranged in quality from prospective randomized trials and retrospective observations to expert opinions.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

In general, the use of sedatives and analgesics in the critically ill adult will provide an optimal level of comfort and safety.

POTENTIAL HARMS

Analgesic therapy

- Repeated dosing of fentanyl may cause accumulation and prolonged effects. Fentanyl also may cause rigidity at high doses.
- With morphine, hypotension may result from vasodilation and an active metabolite may cause prolonged sedation in the presence of renal insufficiency.
- Adverse effects of opioid analgesics are common and occur frequently in intensive care unit patients. Of greatest concern are respiratory, hemodynamic, central nervous system, and gastrointestinal effects. Respiratory depression is a concern in spontaneously breathing patients or those receiving partial ventilatory support. Hypotension can occur in hemodynamically unstable patients, hypovolemic patients, or those with elevated sympathetic tone. Opioid-mediated hypotension in euvolemic patients is a result of the combination of sympatholysis, vagally mediated bradycardia, and histamine release (when using codeine, morphine, or meperidine). Opioid-induced depression of the level of consciousness may cloud the clinical assessment of critically ill patients, and hallucinations may increase agitation in some patients. Gastric retention and ileus are common in critically ill patients, and intestinal hypomotility is enhanced by opioids. Routine prophylactic use of a stimulant laxative may minimize constipation. Small-bowel intubation may be needed for enteral nutrition because of gastric hypomotility. Opioids may increase intracranial pressure with traumatic brain injury, although the data are inconsistent and the clinical significance is unknown.
- Nonsteroidal anti-inflammatory drugs have the potential to cause significant adverse effects, including gastrointestinal bleeding, bleeding secondary to platelet inhibition, and the development of renal insufficiency.
- Prolonged use (more than five days) of ketorolac has been associated with a two-fold increase in the risk of renal failure and an increased risk of gastrointestinal and operative-site bleeding.

Sedative therapy

- Some patients have vivid hypnagogic hallucinations with sedative-amnestic therapy.
- Amnestic sedatives may paradoxically contribute to agitation and disorientation because patients may not remember where they are or why they are in the intensive care unit.
- Continuous infusions of benzodiazepine therapy may produce inadvertent oversedation.
- Long-term or high-dose infusions of propofol may result in hypertriglyceridemia. Other adverse effects most commonly seen include hypotension, bradycardia, and pain upon peripheral venous injection. Elevation of pancreatic enzymes has been reported during prolonged infusions of propofol. Pancreatitis has been reported following anesthesia with propofol, although a causal relationship has not been established. Prolonged use of high doses of propofol has been associated with lactic acidosis, bradycardia, and lipidemia in pediatric patients and doses >83 micrograms/kg/min have been associated with an increased risk of cardiac arrest in adults.
- Rapid administration of dexmedetomidine may produce transient elevations in blood pressure. Patients maintained on dexmedetomidine may develop bradycardia and hypotension, especially in the presence of intravascular volume depletion or high sympathetic tone.
- Patients exposed to more than one week of high-dose opioid or sedative therapy may develop neuroadaptation or physiological dependence. Rapid discontinuation of these agents could lead to withdrawal symptoms.
- Diazepam may cause phlebitis.
- Lorazepam at high does may cause solvent-related acidosis and renal failure.

Delirium therapy

- High doses of haloperidol may cause QT prolongation.
- Neuroleptic agents can cause a dose-dependent QT-interval prolongation of the electrocardiogram, leading to an increased risk of ventricular dysrhythmias, including torsades de pointes.
- Extrapyramidal symptoms (EPS) can occur with use of neuroleptics, including haloperidol.
- Haloperidol therapy for the control of agitation after a traumatic brain injury may prolong the duration of posttraumatic amnesia, but the effect on functional recovery has not been well demonstrated in humans.
- Haloperidol is the most common antipsychotic agent associated with neuroleptic malignant syndrome.

Subgroups Most Likely to be Harmed:

- Patients with hypovolemia or hypoperfusion, the elderly, and those with preexisting renal impairment may be more susceptible to nonsteroidal anti-inflammatory drug-induced renal injury.
- Care must be taken to avoid excessive and potentially hepatotoxic doses of acetaminophen, especially in patients with depleted glutathione stores resulting from hepatic dysfunction or malnutrition. Acetaminophen should be maintained at less than 2 g per day for patients with a significant history of alcohol intake or poor nutritional status and less than 4 g per day for others.

- Accumulation and prolonged sedative effects have been reported in critically ill patients using midazolam who are obese or have a low albumin level or renal failure.
- Patients with a history of cardiac disease are predisposed to QT prolongation with haloperidol.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- The clinical practice guideline issued for 2002 is comprehensive and based on available evidence. This field is still constrained by a dearth of high-quality, randomized prospective trials comparing agents, monitoring techniques, and scoring scales.
- These recommendations in these documents may not be appropriate for use in all clinical situations. Decisions to follow these recommendations must be based on professional judgment, level of care, individual patient circumstances, and available resources.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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the sustained use of sedatives and analgesics in the critically ill adult. Crit Care Med 2002 Jan;30(1):119-41. [235 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1995 (revised 2002)

GUIDELINE DEVELOPER(S)

American College of Critical Care Medicine - Professional Association
American Society of Health-System Pharmacists - Professional Association
Society of Critical Care Medicine - Professional Association

SOURCE(S) OF FUNDING

Society of Critical Care Medicine (SCCM)

American Society of Health-System Pharmacists (ASHP)

GUIDELINE COMMITTEE

Sedation and Analgesia Task Force

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Sedation and Analgesia Task Force Members: Judith Jacobi, Pharm.D., FCCM, BCPS (Chair); Stanley A. Nasraway, Jr, MD, FCCM; (Executive Director of Task Force); H. Scott Bjerke, MD; Donald B. Chalfin, MD, MS, FCCM; William M. Coplin, MD; Douglas B. Coursin, MD; David W. Crippen, MD, FCCM; Dorrie Fontaine, RN, DNSc, FAAN; Gilles L. Fraser, PharmD, FCCM; Barry D. Fuchs, MD; Ruth M. Kelleher, RN; Philip D. Lumb, M.B., B.S., FCCM; Paul E. Marik, MDBCh, FCCM; Michael F. Mascia, MD, MPH; Michael J. Murray, MD, PhD, FCCM; William T. Peruzzi, MD, FCCM; Richard R. Riker, MD, Assistant Chief; Eric T. Wittbrodt, PharmD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

ENDORSER(S)

American College of Chest Physicians - Medical Specialty Society

GUIDELINE STATUS

This is the current release of the guideline. It updates a previously issued version (Practice parameters for intravenous analgesia and sedation for adult patients in the intensive care unit: an executive summary. Society of Critical Care Medicine. Crit Care Med 1995 Sep;23[9]:1596-600).

An update is not in progress at this time.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Society of Critical Care Medicine (SCCM) Web site. Also available from the American Society of Health-System Pharmacists (ASHP) Web site.

Print copies: Available from SCCM, 701 Lee Street, Suite 200, Des Plaines, IL 60016; Telephone: (847) 827-6869; Fax: (847) 827-6886; On-line through the SCCM Bookstore.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Sedation, analgesia, and neuromuscular blockade of the critically ill adult: revised clinical practice guidelines for 2002. Crit Care Med 2002 Jan;30(1):117-8; also published in Am J Health Syst Pharm 2002 Jan 15;59(2):147-9.

Electronic copies: Available from the American Society of Health-System Pharmacists (ASHP) Web site.

Print copies: Available from SCCM, 701 Lee Street, Suite 200, Des Plaines, IL 60016; Telephone: (847) 827-6869; Fax: (847) 827-6886; On-line through the SCCM Bookstore.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on July 22, 2002. The information was verified by the guideline developers on August 1, 2002.

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Date Modified: 11/15/2004